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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
JIANG, SHAOJIA A	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/766,749	KNUTSON ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13 and 15-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13 and 15-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/17/04,9/17/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a Reissue of 08/907,658 filed 08/08/1997 PAT 5,861,386 which is a CON of 08/798,958 filed 02/11/1997 PAT 5,707,980 which is a CON of 08/415,488 filed 04/03/1995 PAT 5,602,116 which is a CIP of 08/119,895 filed 09/10/1993 PAT 5,403,831 which is a CON of 07/812,056 filed 12/17/1991 ABN, which is a CON of 07/569,412 filed 08/17/1990 PAT 5,104,864, which is a CON of 07/227,371 08/02/1988 ABN.

Applicant's preliminary amendment for reissue submitted January 28,, 2004 is acknowledged wherein claims 1-12 and 14 are cancelled; Claim 13 has been amended; claims 15-20 are newly submitted.

Claims 13 and 15-20 are examined on the merits herein.

The reissue oath/declaration filed with this application is defective because it fails to identify at least one error which is relied upon to support the reissue application. See 37 CFR 1.175(a)(1) and MPEP § 1414.

Claim13 and 15-20 are rejected as being based upon a defective reissue oath/declaration under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defect(s) in the oath/declaration is set forth in the discussion above in this Office action, e.g., the statement "[t]his application for reissue is based on at least the error that the full breadth of claim 1 is not supported in accord with the written description requirement of 35 U.S.C. § 112, first paragraph, by the specification

of the patent as filed" in the Application Declaration by the Assignee is not considered to specifically identify at least one error which is relied upon to support the reissue application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13 and 15-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant's preliminary amendment for reissue has been fully considered but is deemed to insert **new matter** into the claims since the specification as originally filed does not provide support for "non-oral dosage form" recited in claim 13. Note that the recitation, "non-oral" encompasses any administration routes other than oral administration which is considered a genus of administration routes. However, the original specification and claims merely disclose several specific administration routes, i.e., as recited in claim 8 now cancelled, which are deemed to be species of administration routes.

Thus, the specification as originally filed does not provide support any "non-oral dosage form", as noted in MPEP 2163, "a subgenus is not necessarily described by a

genus encompassing it and a species upon which it reads", see *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972). In this case, a genus is not necessarily described by specific species.

Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13 and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLuca, Hector F. (US 4225596 PTO-1449 submitted June 17, 2004) in view of Sakhaee et al. ("Postmenopausal osteoporosis as a manifestation of renal hypercalciuria with secondary hyperparathyroidism", PTO-892) and Applicant's admission regarding the prior art in the specification (see 5,861,386, "Background of the Invention" at col.1 line 18-24).

DeLuca discloses that the vitamin D compound having the structural formula therein such as the instant compound, 1α-hydroxyergocalciferol (see col.3 line 22) also known as 1α-hydroxy-vitamin D_2 or 1α-OH-vitamin D_2 (see chemical name provided by

ACS on STN, PTO-892), is useful in a method for treating or preventing the depletion of calcium from the bones of women entering menopause or who are postmenopausal (see col.1 lines 18-22 and 50-51), and a method for increasing the calcium absorption and retention within the body of mammals including humans displaying evidence of, or having a physiological tendency to ward, loss of bone mass, by administering 1α-hydroxyergocalciferol to a human in need thereof such as a postmenopausal woman (see claims 1-5 in particular).

DeLuca discloses that the doses of the instant vitamin D for the methods of the treatment therein are from about 0.1-1 μg (microgram) per day (see col.3 line 30-31). Thus, the dosage amount for a week is (0.1-1 μg per day) X 7 days = 0.7-7 μg per week, which overlaps or within the claimed range. DeLuca discloses the specific non-oral dosage form of the 1α-OH-vitamin D_2 composition such as parenteral by injection or intravenously or by alimentary canal (see col.3 line 28-30).

DeLuca also teaches that other vitamin D compounds, calcium supplement (also known calcium-based phosphate binder), estrogens, fluoride (known as to be administered as sodium fluoride) alone or in combination, are known to be used in the methods of treating bone disorders characterized by loss of bone mass, in particular, postmenopausal osteoporosis (see col.1 line 23-61).

DeLuca does not expressly disclose the employment of the 1α-OH-vitamin D_2 composition in a method for treating a human to alleviate or prevent the pathological effects of hyperparathyroidism secondary to end stage renal disease. DeLuca does not expressly disclose that the vitamin D_2 to be given 1 to 3 times per week.

Sakhaee et al. teaches postmenopausal osteoporosis as a manifestation of renal hypercalciuria with secondary hyperparathyroidism in postmenopausal women (see the abstract in particular).

Moreover, Applicant clearly admits and acknowledges in the specification regarding the prior art that it is known that "renal osteodystrophy is encountered in end-stage renal disease patients undergoing chronic dialysis (see 5,861,386, "Background of the Invention" at col.1 line 18-24).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the 1α-OH-vitamin D_2 composition in a method for treating a human to alleviate or prevent the pathological effects of hyperparathyroidism secondary to end stage renal disease in a human in need thereof, e.g., a postmenopausal woman, and to schedule or program the regimen by administering the vitamin D_2 1 to 3 times per week in the known amount of the prior art.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the 1α-OH-vitamin D_2 composition in a method for treating a human to alleviate or prevent the pathological effects of hyperparathyroidism secondary to end stage renal disease in a human in need thereof, e.g., a postmenopausal woman, since postmenopausal osteoporosis as a manifestation of renal hypercalciuria with secondary hyperparathyroidism is known to be encountered in postmenopausal women according to Sakhaee et al. Moreover, it is known before the invention herein made that "renal osteodystrophy is encountered in end-stage renal

disease patients undergoing chronic dialysis" according to Applicant's admission in the specification.

Thus, the pathological conditions related to the depletion of calcium from the bones of women entering menopause or who are postmenopausal and/or in need of increasing the calcium absorption and retention within the body of mammals including humans displaying evidence of, or having a physiological tendency to ward, loss of bone mass, e.g., in postmenopausal women, taught by DeLuca, would clearly encompass pathological conditions, hyperparathyroidism secondary to end stage renal disease in a human in need thereof as claimed herein, e.g., in a postmenopausal woman.

Therefore, the patient population in DeLuca is deemed to encompass or overlap or coincide the patient herein having osteoporosis and suffering from hyperparathyroidism secondary to end stage renal disease.

Therefore, one of ordinary skill in the art would have reasonably expected that 1α-OH-vitamin D_2, would have beneficial therapeutic effects and usefulness in method for treating a human, e.g., a postmenopausal woman, to alleviate or prevent the pathological effects of hyperparathyroidism secondary to end stage renal disease, by administering the same effective amounts of the same compound of DeLuca to the same or overlapping patient population.

Additionally, scheduling or programming a regimen by administering the vitamin D_2 1 to 3 times per week, or once or twice a day, based on the known amount of the

prior art is deemed obvious since they are all within the knowledge and conventional skills of pharmacologist or a medical practitioner.

Thus the claimed invention as a whole is clearly prima facie obvious over the teachings of the prior art.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (571)272-0627. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. Anna Jiang, Ph.D.
Primary Examiner
Art Unit 1617
March 3, 2005